REMARKS

This is in response to the Office Action of January 15, 2003, the shortened period for response there to expiring April 15, 2003.

The application comprises claims 1-9, claims 1-9 were rejected under 35 USC §102(b) as being anticipated by Arzbaecher, US Patent 5,607,418 in that Arzbaecher discloses an infusion device having a variable volume storage chamber for holding the fluid to be delivered, a pressurizing means for the storage chamber to maintain the pressure in that chamber at a pressure greater then the outflow pressure, an outflow chamber for receiving the fluid from the storage chamber and maintaining that fluid at a preselected pressure, a flow restrictor between the outflow chamber and the patient and a flow regulator means between the storage chamber and the outflow chamber maintaining the pressure of the outflow chamber at a preselected pressure while allowing fluid to be transferred from the storage chamber to the outflow chamber.

It is respectfully submitted that claim 1, as amended, clearly distinguishes over the cited reference and said reference neither shows or suggests the claimed invention. US Patent 5,607,418 to Arzbaecher discloses a drug pump having two deformable fluid filled chambers which have a delivery mass flow rate below a clinically approved level when both flow means 30 and 35 are open. In order to accomplish this, the flow rate of fluid from the outer (storage) chamber 21 into the inner (output) chamber 26 is restricted to a flow rate of 1/10 to 1/150 of the flow rate of the fluid from the inner chamber to the catheter 14. This is accomplished by flow restrictors such as an extended length of narrow conduit, or orifices, or one-way valves.

The Arzbaecher drug pump is not a pump for the continuous delivery of a drug; it is a bolus delivery pump with a slowly filling bolus chamber. The maximum flow rate to the patient is controlled by the pressure of the fluid in the outer (storage) chamber and the flowrate allowed by the flow restrictor between the outer chamber and the inner chamber. The flow restrictor between the inner chamber and the catheter controls the flowrate at which the bolus can be delivered to the patient. That flowrate is 10 times to 150 times greater than the flow rate of fluid into the inner (output) chamber. In order for the Arzbaecher pump to

operate the inner chamber must have a return bias force built into the chamber in order for it to refill after the fluid has been dispensed from that chamber. If this return bias force is not present, the chamber would not refill.

In contrast thereto, applicants' claimed drug pump functions in a completely different manner from the Arzbaecher drug pump. Applicants' pump is a continuous flow delivery drug pump. It has a storage chamber, which is deformable, and contains fluid under a significantly high but adjustable pressure. It also has an outflow chamber that contains fluid at a lower, closely regulated, pressure for delivery to the patient. A pressure regulator is located between the storage and outflow chambers. It is not a flow restrictor; however, it controls the fluid flowing into the outflow chamber by maintaining a constant pressure. As long as the pressure in the storage chamber is greater than the pressure in the outflow chamber, the outflow chamber will fill.

The flow rate of the fluid to the patient is controlled by the regulated pressure in the outflow chamber and the flow restrictor between the outflow chamber and the catheter. If the pressure regulator between the storage chamber and the outflow chamber were kept open, as in the Arzbaecher reference, the flow rate to the patient would be significantly higher and more variable. The flow rate to the patient would depend on the pressure in the storage chamber rather than the closely requested pressure in the outflow chamber.

The outflow chamber of the claimed invention does not empty as in the Arzbaecher drug pump because the flow of fluid from the storage chamber through the pressure regulator is greater than the flow of fluid out of the outflow chamber through the flow restrictor and into the catheter. Further, there is no dispensing valve in applicants' claimed drug pump. Once the catheter, which contains the flow restrictor, is inserted into the elastomeric septum of the drug pump, there is a continuous and uniform flow through the catheter until the pump storage container is empty. In Arzbaecher, a bolus is delivered from the outflow chamber depleting the outflow chamber contents. Flow to the patient then ceases while the outflow chamber refills, followed by another bolus delivery.

Claims 1-9 remain in the application. It is respectively submitted that these claims are patentable, fully supported by the Specification and not shown or suggested by the prior art. It is requested that the claims be found to be patentable and a Notice of Allowance be issued.

Respectfully submitted,

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